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IN THE COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO
CIVIL DIVISION

MARY RAVENSCRAFT **INDIVIDUALLY AND AS A CLASS** **REPRESENTATIVE** **5247 MADISON PIKE** **INDEPENDENCE, KY 41051**	:	Case No. A 1602066 Judge
Plaintiffs,	:	**COMPLAINT** **& JURY DEMAND** **(CLASS ACTION)**
JOURNEY LITE OF CINCINNATI, LLC 10475 READING RD., SUITE 115 CINCINNATI, OH 45241 SERVE: CT CORPORATION SYSTEM 1300 EAST NINTH STREET CLEVELAND, OH 44114 (Serve via Certified mail)	:	(ALL NEW DR. DURRANI CASES SHALL GO TO JUDGE RUEHLMAN PER HIS ORDER. THIS CASE INVOLVES DR. DURRANI LITIGATION SO THIS CASE SHALL BE ASSIGNED TO JUDGE RUEHLMAN) REGULAR MAIL WAIVER
Defendants.	:	

Comes now Plaintiffs, by and through counsel, and files this Complaint and jury demand, stating as follows:

1. This Court has subject matter jurisdiction over this matter pursuant to Ohio Revised Code §2305.01.

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2. Plaintiffs are patients who without their knowledge had Puregen implanted in them during surgery by Dr. Atiq Durrani at Journey Lite, which is owned by Journey Lite LLC which is located in Hamilton County, Ohio. Many members of the Class are also residents of Hamilton County, Ohio.

3. At all times relevant herein, Defendants held themselves out to the public, including by

EXHIBIT A

their marketing and promotional campaigns and specifically to Plaintiffs, as a hospital providing competent and qualified medical and nursing services, care and treatment by and through its physicians, physicians in training, residents, nurses, agents, ostensible agents, servants and/or employees.

4. Plaintiff and class representative Mary Ravenscraft had surgery at Journey Lite February 15, 2013.
5. The amount in controversy exceeds the jurisdictional threshold of this Court.
6. The subject matter of the Complaint arises out of medical treatment by the Defendants at Journey Lite LLC which is owned by Journey Lite LLC, located in Hamilton County, Ohio. This Court is thus the proper venue to grant the Plaintiffs the relief they seek.
7. Plaintiff Class Members are citizens and residents of the United States who had surgery or medical treatment performed on them at Journey Lite without the benefit of being informed PureGen was used on them during surgery by Dr. Atiq Durrani. Defendant not only breached their duties, they intentionally breached these duties to the detriment of the Plaintiffs.
8. This lawsuit is for any PureGen patient at Journey Lite that Dr. Durrani implanted PureGen in who is not already a Deters Law Office or other law office client who has brought a claim for PureGen.
9. Upon information and belief Dr. Durrani while at West Chester Hospital ("WCH")/ UC Health would take Puregen from the WCH/UC Health facility and use it in Surgery at Journey Lite.

FACTUAL ALLEGATIONS

10. The Deters Law Firm, P.S.C., represents approximately 500 Plaintiffs in medical malpractice actions against a former Northern Kentucky/Cincinnati-area spine surgeon named Abubakar Atiq Dr. Durrani (Dr. Durrani), his company, Center for Advanced Spine Technologies, Inc. (CAST), and several area hospitals including, but not limited to, Journey Lite Hospital, Riverview, and West Chester Hospital/UC Health.

11. Journey Lite is a medical facility in Ohio where Dr. Durrani had surgical privileges from approximately 2011 through approximately 2013.

12. WCH/UC Health is a medical facility in Ohio where Dr. Durrani had surgical privileges from approximately 2009 through approximately 2013.

13. Dr. Durrani is a citizen of the Republic of Pakistan and was a permanent resident of the United States who, from approximately 2005 to 2013, worked as a spine surgeon in and around Cincinnati, Ohio, until he fled the United States to escape civil liability and criminal prosecution.

14. Alphatec Spine, Inc. is a corporation under the laws of California, and jointly developed and distributed PureGen in the State of Ohio.

15. Alphatec Holdings, Inc. is a holding corporation formed under the laws of Delaware with no operations separate from the holding of other companies which owns Alphatec Spine, Inc.

16. Dirk Kuyper was President and CEO of Alphatec Holdings, Inc. from February 2007 to August 2012.

17. Parcell Labratories, LLC is organized under the laws of Delaware and jointly developed Puregen.

18. Alphatec and Parcell co-developed the product "PureGen", and both expected PureGen would be initially limited in application.

19. PureGen is produced and distributed by Alphatec Spine, LLC, a division of Alphatec Holdings.

20. CAST was a corporation organized under the laws of Ohio and had business and medical offices in Florence, Kentucky and Evendale, Ohio. CAST was owned, in whole or in part, by Dr. Durrani.

21. Dr. Durrani performed unnecessary, fraudulent, dangerous, and ultimately damaging surgeries on these Plaintiffs while working for and with Journey Lite.

22. The scheme and artifice to defraud that Dr. Durrani devised, executed, and attempted to execute while working at Journey Lite included the following patterns and practices:

    a. Dr. Durrani persuaded the patient that surgery was the only option, when in fact the patient did not need surgery.

    b. Dr. Durrani told the patient that the medical situation was urgent and required immediate surgery. He also falsely told the patient that he/she was at risk of grave injuries without the surgery.

    c. Dr. Durrani often told his cervical spine patients that they risked paralysis or that his/her head would fall off if he/she was involved in a car accident, ostensibly because there was almost nothing attaching the head to the patient's body.

    d. Dr. Durrani often ordered imaging studies such as x-rays, CT scans, or MRIs for patients but either did not read or ignored the resulting radiology reports.

e. Dr. Durrani often provided his own exaggerated and dire reading of the patient's imaging study that was either inconsistent with or was plainly contradicted by the radiologist's report. At times, Dr. Durrani provided a false reading of the imaging.

f. Dr. Durrani often dictated that he had performed certain physical examinations and procedures on patients that he did not actually perform.

g. Dr. Durrani often ordered a pain injection for a level of the spine that was inconsistent with the pain stated by the patient or with that indicated by the imaging. Dr. Durrani also scheduled patients for surgeries without learning of or waiting for the results of certain pain injections or related therapies.

h. Dr. Durrani often dictated his operative reports or other patient records months after the actual treatment had occurred.

i. Dr. Durrani's operative reports and treatment records contained false statements about the patient's diagnosis, the procedure performed, and the instrumentation used in the procedure.

j. When a patient experienced complications resulting from the surgery, Dr. Durrani at times failed to inform the patient of, or misrepresented the nature of, the complications.

k. All of the above-mentioned actions were done with the knowledge, cooperation, or intentional ignorance of Journey Lite because Dr. Durrani was one of the biggest moneymakers for Journey Lite.

23. In addition to the civil medical malpractice actions against Dr. Durrani, on August 7, 2013, he was indicted by the Federal Government for performing unnecessary surgeries and for

defrauding the Medicare and Medicaid programs. Specifically, the ten-count complaint charged Dr. Durrani with health care fraud, in violation of 18 U.S.C. § 1347, and making false statements in health care matters, in violation of 18 U.S.C. § 1035. There was a subsequent superseding indictment which covered over 30 counts.

24. Following these criminal indictments, in December of 2013 and prior to the first Plaintiff's trial in these actions, Dr. Durrani fled the United States and returned to Pakistan. He has not returned to the United States to face allegations of either criminal or civil liability.

25. Among Dr. Durrani and various hospitals professional failings, was the use of a non-FDA approved stem cell based implant called PureGen in at least 82 clients without their informed consent.

26. Dr. Durrani predominately used PureGen on patients at Journey Lite

27. It is Plaintiffs' position that this use of a non-FDA approved biologic such as PureGen was not only negligent, it is criminal.

28. The FDA stated that PureGen, "does not meet all of the criteria in 21 CFR 1271.10(a) and therefore is not regulated solely under section 361 of the Public Health Service Act and the regulations in 21 CFR Part 1271. Specifically, the product does not meet the criterion in 21 CFR 1271.10(a)(4)(ii)(b) because the product is dependent on the metabolic activity of living cells for its primary function."

29. As a result, a valid biologics license was required, which was never obtained by Alphatec or Parcell labs in regards to PureGen.

WHAT IS PUREGEN?

30. The full name of Puregen is PureGen Osteoprogenitor Cell Allograft (PureGen) is a highly concentrated, pure population of Early Lineage Adult (ELA) stem cells that originates in bone marrow and is collected from live, healthy donors.

31. PureGen's purpose was to facilitate bone fusion by mimicking the regenerative environment of youthful tissues by increasing the concentration of stem cells available to repair tissue and build bone.

32. When used off-label, biologic bone allograft frequently causes excessive or uncontrolled (also referred to as "ectopic" or "exuberant") bone growth on or around the spinal cord.

PUREGEN AS A BIOLOGIC

33. Puregen is not a device, but instead it is a biologic. *See* July 2009 American Medical Association Article and 2011 Stanford School of Medicine Article.

34. According to the FDA, "[a] 'biological product' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings (Public Health Service Act Sec. 351(i)1." Available at http://www.fda.gov/ICECI/Inspections/IOM/ucm122535.htm.

35. PureGen is harvested from living human beings under the Stem Cell Collection Program administered by the Food and Drug Administration (FDA) and is defined as both a "biologic" by 42 U.S.C. 351(i) and a "drug" as defined by U.S.C. 321(g).

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[1] It should be noted that a biologic can also meet the definitions of drug or device. http://www.fda.gov/ICECI/Inspections/IOM/ucm122535.htm

36. PureGen's purpose was to facilitate bone fusion by mimicking the regenerative environment of youthful tissues by increasing the concentration of stem cells available to repair tissue and build bone.

37. A patient has a right to determine what happens to his or her body and the preservation of that right requires that the patient be informed when a bone growth product, that causes irreversible harm, is placed in his or her body.

WHEN IS IT USED?

38. PureGen's purpose was to facilitate bone fusion by mimicking the regenerative environment of youthful tissues by increasing the concentration of stem cells available to repair tissue and build bone.

RISKS ASSOCIATED WITH OFF-LABEL USE

39. **PUREGEN WAS NEVER APPROVED BY THE FDA FOR USE IN HUMANS**

40. When used in an off-label manner, biologic bone allograft frequently causes excessive or uncontrolled (also referred to as "ectopic" or exuberant") bone growth on or around the spinal cord.

41. When nerves are compressed by such excessive bone growth, a patient can experience, among other adverse events, intractable pain, paralysis, spasms, and cramps in limbs.

42. **THE REGULATORY PROCESS**

43. PureGen was entered into 3 clinical trials by Alphatec on or around February 9, 2011 which were scheduled to last until September of 2013.

44. The study population were 50 male/female subjects 18 years and older suffering from symptoms of cervical degenerative disc disease in one to four contiguous levels between C3 and T1.

45. The clinical trial required:

a. Inclusion

i. Age over 50

ii. Side-by-side use of Puregen and Autologous bone in the same patient for radiographic comparison

iii. Symptomatic lumbar degenerative disc disease in up to 2 contiguous levels between L1 and S1

iv. Subjects with back and/or leg paint indicated for posterior stabilization with or without decompression at any level and posteriolateral fusion

v. Unresponsive to conservative treatment for at least 6 months

vi. Radiographic evidence of primary diagnosis

b. Exclusion:

i. No healthy volunteers permitted

ii. More than two levels requiring posteriolateral fusion (PLF)

iii. Spondyliosis greater than Grade 1

iv. Prior failed fusion surgery at lumbar level(s)

v. Systemic or local infection in the disc or cervical spine, past or present

vi. Active systemic disease

vii. Osteoporosis, Osteomalacia, or other metabolic bone disease that would significantly inhibit bone healing

viii. BMI greater than 40

ix. Use of post operative spinal cord stimulator

x. Known or suspected history of alcohol and/or drug abuse

xi. Involved in pending litigation or worker's compensation related to the spine

xii. Pregnant or planning to become pregnant during the course of the study

xiii. Insulin-dependent diabetes mellitus

xiv. Life expectancy less than duration of study

xv. Any significant psychological disturbance that could impair consent process or ability to complete self-assessment questionnaires

xvi. Undergoing chemotherapy or radiation treatment, or chronic use of oral or injected steroids or prolonged use of non-steroidal anti-inflammatory drugs

xvii. Known history of hypersensitivity or anaphylactic reaction to dimenthyl sulfoxide (DMSO).

46. All 3 clinical trials were "Terminated" before any results were produced. See Summary of Clinical Trials obtained from clinicaltrials.gov.

47. Alphatec and Parcell saw this limited approval for clinical trials as an opportunity to market PureGen without premarket approval, 510K clearance, an exception to the Food Drug and Cosmetic Act, meeting the humanitarian device exception, investigational new drug (IND) application, or other permission to market PureGen, all in violation of the Food Drug and Cosmetic Act.

48. Alphatec and Parcell began a course of conduct designed to expand the application of PureGen by end users in excess of the approved clinical trial of PureGen. This course of conduct utilized fraud, false statements, material misrepresentation, and deceit in order to broaden the sales of PureGen beyond that which the usual acceptance within the scientific community or regulatory approval would otherwise allow.

49. The Food and Drug Administration (FDA) conducted an inspection of Parcell Laboratories between February 9-14, 2011.

50. After the inspection, the FDA responded quickly to the unlicensed marketing of the device PureGen by warning that PureGen was not the subject of an IND application nor a valid biologics license with a letter dated June 23, 2011.

51. The letter stated that the cells used in the production of PureGen were human cells, tissues, or cellular and tissue-based products (*HCT/Ps*) as defined in 21 CFR 1271.3(d).

52. Based on this analysis, the FDA determined that PureGen was a drug and biological product as defined in the Federal Food, Drug and Cosmetic Act.

53. According to the Public Health Service Act, a valid biologics license is also required to introduce a biologics device to the market.

54. Alphatec Spine did not acquire a valid biologics license to enter a biologics product into interstate commerce, in violation of 21 U.S.C. 355(a); 42 U.S.C. 262(a).

55. both the Federal Food, Drug and Cosmetic Act and the Public Health Service Act.

56. **ALPHATEC & PARCELL LABORATORIES**

57. In a statement to the press approximately a week after receiving the FDA Letter, Alphatec President Dirk Kuyper stated, "Both Alphatec Spine and Parcell Laboratories are fully committed to work closely and collaboratively with the FDA to address the questions related to

the PureGen Product. We look forward to discussing the PureGen product with the FDA and sharing our clinical outcomes to date." See article "Alphatec comments on FDA's letter regarding PureGen product for spinal fusion procedures", Spinal News International, July 28, 2011.

58. No such cooperation by Alphatec and Parcell labs occurred and no clinical outcomes were shared with the FDA as all clinical trials of PureGen were "Terminated" and no data was released as to the findings.

59. In fact, Alphatec and Parcell responded to this letter by continuing to market PureGen in an unlicensed manner until Alphatec finally acknowledged the letter in or around February 2013, almost two years after receiving the letter, by stating it disagrees with the FDA's classification of PureGen as anything other than a tissue product – despite the clinical trial approval listing PureGen as "Biological: PureGen Osteoprogenitor Cell Allograft".

60. Furthermore, according to representative Thomas Blank, Alphatec falsely informed distributors of PureGen that they "resolved" the issues addressed in the FDA letter, did not have to take PureGen off the market and it was "ok" for their distributors to continue marketing and selling PureGen.

61. Despite the approval for the clinical trial of PureGen which limited enrollment to 50 patients, Alphatec advertised in its 2012 Annual Report that PureGen had been implanted in over 3,500 patients.

62. PureGen further stated that it had been placed in these 3,500 patients with "no adverse events related to the product", despite no study, statistics or information to back up such a claim.

63. The 2012 annual report also identified PureGen as a biologic.

64. In the First Quarter of 2011, Alphatec Spine attributed part of its 40.9% increase in revenue to the PureGen product. See Becker's Spine Review, Alphatec Spine Reports $49.7M in Q1 Revenue, 40.9% Increase, May 5, 2011.

65. Eventually, after PureGen had been unlawfully implanted in thousands of patients, Alphatec and Parcell conceded that PureGen is a tissue product and a biologic and stopped shipping PureGen in February of 2013.

PUREGEN AND OHIO LAW

66. It is the position of the Plaintiffs that the distribution and use of PureGen by Dr. Durrani while at Journey Lite,WCH/UC Health, Evolution Medical, Alphatec Spine, Inc, Riverview, and various area hospitals is in violation not only of Federal Law as outlined in the FDA's letter, but Ohio State Law as well.

67. Ohio Revised Code 3715.65(A) states that "No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug unless an application with respect to the drug has become effective under section 505 of the Federal Food, Drug and Cosmetic Act, 52 Stat. 1040 (1938), 21 U.S.C.A. 301".

68. A "New Drug" is defined as "Any drug the composition of which is not generally recognized among experts by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof." Ohio Revised Code 3715.01(9)(a).

69. PureGen's status as a Biologic further supports the classification of a drug under the FDA and Ohio Law: "A "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound),

applicable to the prevention, treatment, or cure of a disease or condition of human beings (Public Health Service Act Sec. 351(i)). Additional interpretation of the statutory language is found in 21 CFR 600.3. Biological products also meet the definition of either a drug or device under Sections 201(g) and (h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)." See http://www.fda.gov/ICECI/Inspections/IOM/ucm122535.htm.

70. It is the position of the Plaintiffs that PureGen is a drug as defined in ORC 3715.01 and that its distribution before FDA approval was in violation of ORC 3715.65(A).

Journey Lite, West Chester Hospital/UC Health and PUREGEN

71. Upon information and belief Dr. Durrani while at West Chester Hospital ("WCH")/ UC Health would take Puregen from the WCH/UC Health facility and use it in Surgery at Journey Lite.

72. On October 10, 2011, UC Health began purchasing PureGen from Alphatec.

73. Thomas Blank was an employee of Innovative Medical Consultants, LLC and a sales representative, seller, marketer, and distributer of PureGen for the Northern Kentucky/Cincinnati area.

74. In his professional capacity, Thomas Blank was present during most, if not all, of the surgeries at issue where PureGen was secretly implanted into various Plaintiffs without informed consent or permission.

75. Thomas Blank worked directly with Alphatec Spine, Inc in the marketing and distribution of PureGen.

76. Additionally, Thomas Blank is a shareholder in Alphatec Spine, Inc..

77. On May 10, 2012 Evolution Medical, LLC, a physician owned distributorship (POD), owned in part (at least 40%) by Dr. Durrani and incorporated in Delaware, received a Kentucky Certificate of Authority. See Commonwealth of Kentucky Certificate of Authority.

78. Around this time, Thomas Blank began to work with Evolution Medical in the marketing and distribution of PureGen, in addition to his dealing with Alphatec Spine, Inc.

79. On July 20, 2012, UC Health began purchasing PureGen from Evolution Medical, LLC. See Evolution Medical Invoices.

80. The purchase of PureGen, the logistics of the billing, the bills of lading, the receiving and handling of PureGen for West Chester Hospital/UC Health was handled by UC Health Purchasing.

81. UC Health and WCH tracked their purchases of PureGen from Evolution medical. See PureGen Tracking Forms.

82. Specifically, Thomas Blank would provide the materials from Alphatec related to the use and approval of PureGen to Dwayne Brown on behalf of UC Health, who would request PureGen based on the amounts requested by Dr. Durrani while at WCH/UC Health.

83. After the UC Health reps approved the use of PureGen, Thomas Blank and his associate Toby Wilcox would order the product, typically in bulk, and draft the requisite billing documents.

84. The PureGen ordered would be stored on site at WCH in the freezer of the operating rooms.

85. In addition to Dr. Durrani, other doctors at WCH used PureGen, including Dr. Chunduri, Dr. Curt and Dr. Shanti.

86. WCH and UC Health would purchase and allow these doctors to use a substance not approved by the FDA in patients without their informed consent.

87. Though WCH and UC Health do have patients fill out "informed consent" forms, no mention of PureGen or its non-FDA approved status is mentioned on these forms.

DR. DURRANI WHILE AT JOURNEY LITE AND PUREGEN

88. Dr. Durrani oftentimes used Puregen when performing surgeries.

89. Puregen is a product produced by Alphatec Spine.

90 Dr. Durrani was and is a paid consultant for Alphatec Spine.

91. Dr. Durrani has an ownership stake in the Alphatec Spine.

92. Puregen has never been approved by the FDA for any human use.

93. Puregen is now removed from the market for any use.

94. Dr. Durrani used the product Puregen as bone graft substitute similar to Infuse/BMP-2 during spinal surgeries.

95. Dr. Durrani and Journey Lite personnel did not disclose their intent to use Puregen, nor did they inform Plaintiff that it was a product that was not approved by the FDA for human use.

96. Dr. Durrani used Puregen in Plaintiff in manners not approved by the FDA.

97. Plaintiff was not informed by Dr Durrai or any Journey Lite personnel that Dr. Durrani used Puregen in her surgeries.

98. Plaintiff would not have allowed Puregen to be used by Dr. Durrani in her surgeries in a manner that was not approved by the FDA.

99. Plaintiff would not have consented to the use of Puregen in their body if informed of the risks by Dr. Durrani or any Journey Lite personnel.

100. The written informed consent of Dr. Durrani and Journey Lite signed by Plaintiff lacked the disclosure of Puregen's use in their procedures.

101. Plaintiff never received a verbal disclosure of Puregen from Dr. Durrani, CAST staff and employees, or any West Chester/UC Health personnel.

102. Upon information and belief Dr. Durrani while at West Chester Hospital ("WCH")/ UC Health would take Puregen from the WCH/UC Health facility and use it in Surgery at Journey Lite.

103. In one of the few depositions taken of Dr. Durrani before his flight from the country he stated that PurGen is "essentially stem cells" and that he "used to use [PureGen] for a certain amount of time."

104. This "certain amount of time" was approximately 3 years between 2010 and 2013, all while PureGen remained unapproved by the FDA.

105. Though downplaying his involvement with PureGen, Dr. Durrani, through his POD Evolution Medical, distributed PureGen to various Hospitals including WCH which was then transported and used at Journey Lite.

106. Dr. Durrani and his Evolution Medical co-owner Toby Wilcox knew the Department of Health and Human Services and the United States Senate Finance Committee has released reports on dangers of Physician-owned entities, notably Physician-owned Distributorships (POD's). See Senate Reports on Physician Owned Distributorships.

107. Dr. Durrani while at Jounrey Lite and Toby Wilcox's actions through Evolution Medical violated the Anti-Kickback Statute 42 U.S.C. 1320 and Stark Law 42 U.S.C. 1395.

108. Compliance with the Anti-Kickback Statutes is a condition of receiving payment from a Federally-funded healthcare program, and most private insurers have a parallel conditional requirement.

109. The Anit-Kickback Statute prohibits the payment and receipt of kickbacks in return for either procuring or recommending the procurement of a good, facility, or item to be paid in whole or in part by a federal healthcare program. 42 U.S.C. 1320a-7b(b).

110. In violation of 45 C.F.R. 46, and in furtherance of the scheme to feign avoidance of the anti-kickback statutes, Dr. Durrani while at Journey Lite, Riverview, WCH/UC Health, CAST, Alphatec and the hospitals experimented on patients by using PureGen in unapproved manners, without the informed consent of the patients, and subsequently billing their health insurance companies all while concealing the true nature of their actions.

111. Dr. Durrani while at WCH/UC Health also had connections with Alphatec as his personal calendar indicates meetings with Dirk Kuyper, President and CEO of Alphatec in 2008.

112. Dr. Durrani while at Journey Lite and WCH/UC Health experimentally used Puregen bone graft in twenty cervical surgeries, along with as many as 72 thoracic, cervical, and lumbar surgeries, ignoring the limited uses it was approved for in the clinical trials.

113. Dr. Durrani while at Journey Lite and WCH/UC Health, through his POD Evolution Medical, was essentially "double dipping" in his dealings with PureGen.

114. Dr. Durrani while at Journey Lite and WCH/UC Health would sell WCH and the other hospitals such as Journey Lite and Riverview PureGen through Evolution Medical and then use and bill for the PureGen in his surgeries. Upon information and belief this occurred at Journey Lite.

115. Dr. Durrani while at Journey Lite knew such an arrangement was either unethical or questionable at best (though still not disclosing the use of PureGen), having his patients sign an Acknowledgement of Potential Conflict of Interest form. See CAST Acknowledgement of Potential Conflict of Interest form.

116. Journey Lite also benefited from this arrangement by up charging patients for the PureGen after purchasing from Evolution Medical and Dr. Durrani.

117. At all times relevant, Dr. Durrani while at Journey Lite and WCH/UC Health was in exclusive control of the amount and ratio of Puregen bone graft that was experimentally implanted into patients.

118. PureGen was and remains unapproved by the FDA for use in humans without an Investigation New Drug ("IND") or experimental informed consent of the patient.

119. Dr. Durrani while at Journey Lite did not receive experimental informed consent from patients, nor did he verify that an IND was obtained.

120. The basic "Informed Consent Forms" Dr. Durrani while at Journey Lite, did have patients fill out made no mention of PureGen or the fact a non-FDA approved product was being implanted in their body. In fact, Dr. Durrani while at Journey Lite would even conceal the use of PureGen by intentionally withholding it from the billing records, noting on one Pre-Op Code sheet "Do Not Bill" twice in regards to PureGen.

121. Implanting Puregen in any part of the spinal canal without FDA clearance, proper trials, and patient consent is reckless battery and violates the Hippocratic Oath's statement "I will prescribe regimens for the good of my patients according to my ability and my judgment and never **do harm** to anyone." It is also criminal.

PUREGEN AND OUR CLIENTS

122. What follows are just a few examples of the damage caused by Dr. Durrani while at Journey Lite and Journey Lite's deceptive and fraudulent use of PureGen in our clients without their consent.

123. A majority of these surgeries occurred AFTER the FDA inspection and subsequent warning on the non-FDA approved status of PureGen.

124. Following the cervical surgeries in which Puregen was implanted, the clients pain became far worse and more extreme.

125. The patients attest to difficulty with swallowing unthickened liquid, medications in pill form, routine saliva, and food.

126. Many patients describe a choking sensation felt on a daily basis when swallowing and changes to the tone and audibility of their voice, along with a chronic cough.

127. Following the thoracic and lumbar surgeries, patients attest to increased spinal pain, difficulty with ambulation, numbness and tingling in lower extremities, decreased flexibility.

128. Below are some of the clients experiences since having the Puregen implanted:

129. "Severe spin in my neck, arm, shoulder blades. Pressure on my throat making it unbearable to swallow meds and food. Loss of range of motion in my neck and stiffness in back. The pain is so severe that I can no longer sleep laying down. I have to sleep sitting up. The pain in my neck is unbearable most days. The pain runs between my shoulder blades into my chest and in my throat and side of my neck." - Duane Pelfrey

130. "I feel I have lost a lot of the flexibility in my neck and back. I have lower back pain, tightness in neck and shoulders, and have a hard time lifting/standing for long periods of time. When I bend over, I have a hard time straightening back up to an upright position." - Dana Conley

131. "I experience pounding headaches that are far worse than anything prior to surgery. Left leg is numb, painful and swollen, muscle spasms occurring in hip and bilateral legs since

surgeries with Dr. Durrani. My whole back, neck and leg hurt so bad I could throw up." - Tonia McQueary.

FACTUAL SCENARIOS OF CLIENT SURGERIES WITH PUREGEN

MICHELLE AGEE

132. Plaintiff sought treatment with Dr. Durrani in May 2012 for back pain radiating into her legs.

133. Dr. Durrani recommended surgery to alleviate Plaintiff's pain.

134. On April 26, 2013 Dr. Durrani performed a transforaminal lumbar interbody discetomy and fusion and posterior spinal fusion on Plaintiff at Journey Lite.

135. Plaintiff followed up with Dr. Durrani complaining of increased and new pain in her back and lower back.

136. Dr. Durrani recommended a second surgery based on the pain and her reports of weakness in her legs and feet following surgery. Dr. Durrani informed Plaintiff her hardware had migrated and revision surgery was necessary to replace and correct the first surgery.

137. On June 13, 2013 Dr. Durrani performed a revision transformainal lumbar interbody fusion on the left side as well as a placement of TLIF cage on left side.

138. Following surgery Plaintiff had increased pain and is unable to perform everyday tasks any longer.

139. Upon information and belief, Dr. Durrani used Infuse/BMP-2 "off –label" and/or Puregen without Mrs. Agee's knowledge or consent, causing Mrs. Agee harm.

140. Upon information and belief, the surgeries performed by Dr. Durrani were medically unnecessary and improperly performed.

141. As a direct and proximate result of Mrs. Agee's surgeries, Dr. Durrani's negligence, and the Defendant's negligence, Mrs. Agee has suffered harm.

142. Plaintiff did not become aware of Infuse/BMP-2 and/or Puregen until she contacted her undersigned counsel.

DANA CONLEY

143. In late 2012, Plaintiff visited Dr. Abbot at Middletown Sports Medicine for lower back pain, neck pain, and numbness in his extremities.

144. Upon Dr. Abbot's recommendation, Plaintiff visited Dr. Durrani at CAST.

145. At Plaintiff's initial visit, Dr. Durrani ordered x-rays, steroid injections, and told Plaintiff he needed to undergo neck surgery with him immediately.

146. At a follow-up visit, Dr. Durrani told Plaintiff he needed back surgery as well.

147. On December 1, 2012, Dr. Durrani performed a fusion on Plaintiff's cervical spine at C5–6 at Journey Lite.

148. Upon information and belief, during this surgery, Dr. Durrani used Infuse/BMP-2 or PureGen "off-label" without Plaintiff's knowledge or consent, causing harm.

149. Specifically, Plaintiff began losing nearly all of his flexibility in his neck and back.

150. Nonetheless, Plaintiff continued treating with Dr. Durrani who told him he would heal and that it just takes time to do so.

151. On February 13, 2013, Dr. Durrani performed a spinal fusion on Plaintiff at L5-S1 at West Chester Hospital.

152. Upon information and belief, Dr. Durrani once again used Infuse/BMP-2 or Puregen "off-label" without Plaintiff's knowledge or consent, causing harm.

153. Plaintiff followed up with Dr. Durrani at CAST each month after his surgery for three months.

154. After this second surgery, Plaintiff continued having neck and back stiffness, and additionally, began experiencing severe neck and lower back pain, which radiates to his shoulders.

155. This pain and stiffness still exists, making it difficult for Plaintiff to stand straight, bend,

and lift.

156. Upon information and belief, both surgeries performed by Dr. Durrani were medically unnecessary and improperly performed.

157. As a direct and proximate result of these surgeries and Dr. Durrani's actions, Plaintiff has suffered harm.

158. Plaintiff was not aware of Dr. Durrani's use of Infuse/BMP-2 or PureGen until he contacted his undersigned counsel.

JOI CROWE

159. Plaintiff was referred to seek treatment with Dr. Durrani in April 2009 for lower back pain.

160. Dr. Durrani diagnosed Plaintiff with spinal stenosis, a bulging disk and arthritis.

161. Dr. Durrani suggested steroid injections for her pain.

162. Although Plaintiff had not complained of neck pain, Dr. Durrani informed her she had a very serious neck issue and needed surgery. He told her she was living on borrowed time and without surgery would be paralyzed or worse.

163. On May 13, 2009 Dr. Durrani performed a cervical fusion on Plaintiff at Christ Hospital.

164. Plaintiff continued to follow up with Dr. Durrani and complain of her ongoing back pain.

165. On December 7, 2009 Dr. Durrani performed a lumbar fusion on Plaintiff at West Chester Medical Center.

166. Plaintiff continued to have extreme back pain following this surgery.

167. Plaintiff also began having intense pain in her hips making it difficult to walk.

168. On November 2, 2012 Dr. Durrani performed a laminectomy on Plaintiff at Journey Lite.

169. Plaintiff was still having extreme and worsening pain following this surgery.

170. Dr. Durrani recommended yet another surgery.

171. On January 11, 2013 Dr. Durrani performed a spinal fusion on Plaintiff at Journey Lite.

172. Plaintiff's pain in her back and hips has increased dramatically after all of her surgeries.

173. Plaintiff's quality of life has diminished because of pain and discomfort caused by the surgeries.

174. Upon information and belief, Dr. Durrani used Infuse/BMP-2 "off-label," without Plaintiff's knowledge or consent, causing Plaintiff harm.

175. Upon information and belief, the surgeries performed by Dr. Durrani were medically unnecessary and improperly performed.

176. As a direct and proximate result of the surgeries and Dr. Durrani's actions, Plaintiff has suffered harm.

177. Plaintiff did not become aware of Dr. Durrani's use of Infuse/BMP-2 in him until she contacted her undersigned counsel.

ERIN GREELISH

178. Plaintiff was referred to Dr. Durrani in 2011 by Dr. Brad Tinkle of Cincinnati Children's Hospital.

179. At the time, Plaintiff was experiencing headaches that originated at the intersection of her spine and neck, and which caused her severe pain and dizziness.

180. Dr. Durrani ordered Plaintiff to undergo MRI and CAT scan procedures.

181. During his consultation with Plaintiff, Dr. Durrani applied pressure to the back of Plaintiff's head and neck, resulting in her losing consciousness.

182. Dr. Durrani told the Plaintiff that she would need to have a fusion of C1-C2 as well as C1-Occiput or she would likely suffer an "internal decapitation."

183. Dr. Durrani did not fully explore conservative treatment options prior to recommending this surgery.

184. On December 21, 2011 Dr. Durrani performed surgery on the Plaintiff consisting of a cervical fusion from C1-C2 at West Chester Hospital ["the first surgery"].

185. Upon information and belief, Dr. Durrani used Infuse/BMP-2 or Puregen "off-label" in this first surgery without Plaintiff's knowledge or consent, causing harm.

186. Plaintiff received follow-up treatment from Dr. Durrani and CAST.

187. After her six-week postoperative appointment, Plaintiff was given a cervical collar and told to "wean [herself] off of the collar."

188. Plaintiff received no other physical therapy.

189. Plaintiff began to suffer from different pains following this surgery, but was assured by Dr. Durrani that her recovery would likely be slow, but certain.

190. Plaintiff also lost a measure of her mobility and flexibility in her neck after this surgery, and is unable to move her head through its full range of motion.

191. Plaintiff returned to Dr. Durrani in late 2012 after she began to suffer from intense pain in the area of her previous surgery. Dr. Durrani ordered her to undergo more MRI procedures.

192. Dr. Durrani told Plaintiff that he "really just needed to fix C5-C6," though the MRI report indicated that her previously operated on C1-C2 was not showing any signs of fusion.

193. On November 16, 2012 Dr. Durrani performed surgery on the Plaintiff consisting of a cervical fusion from C5-C6 at Journey Lite ["the second surgery"].

194. Upon information and belief, Dr. Durrani used Infuse/BMP-2 or Puregen "off-label" in this second surgery without Plaintiff's knowledge or consent, causing harm.

195. Plaintiff continued to receive follow-up treatment from Dr. Durrani and CAST.

196. Plaintiff continued to see Dr. Durrani until early 2013.

197. Plaintiff now has a very limited range of motion and severe pain that radiates from the base of her skull. She suffers from constant, severe pain that has only intensified since her surgeries with Dr. Durrani.

198. Upon information and belief, the surgery performed by Dr. Durrani was medically unnecessary and improperly performed.

199. As a direct and proximate result of these surgeries and Dr. Durrani's negligence, the Plaintiffs have suffered harm.

200. Plaintiffs did not become aware of Dr. Durrani's use of Infuse/BMP-2 until legal counsel reviewed Plaintiffs' bills.

TIMOTHY HANNON

201. Plaintiff was referred to Dr. Durrani at his CAST offices in northern Kentucky in October 2011 by Dr. Emmit Roper.

202. At the time Plaintiff was experiencing sharp neck pains, as well as pain and numbness down his left leg and arm.

203. Dr. Durrani immediately recommended surgery to correct Plaintiff's pain, in addition to the administration of epidural shots in Plaintiff's neck.

204. Upon information and belief, in March 2012 Dr. Durrani performed surgery on the Plaintiff consisting of a cervical spinal fusion from C4-C7 at West Chester Hospital ["the first surgery".]

205. Upon information and belief, Dr. Durrani used Infuse/BMP-2 or Puregen "off-label" in this first surgery without Plaintiff's knowledge or consent, causing harm.

206. After this surgery, Plaintiff received postoperative care from CAST in Blue Ash.

207. Though Plaintiff's numbness in his leg and arm began to recede after this surgery, he began to suffer from restrictions in turning his head. Additionally Plaintiff started to have difficulty swallowing, and developed a metallic taste in his mouth that would not go away.

208. Dr. Durrani told the Plaintiff that it would take approximately a year to recover, and that Plaintiff would likely require more injections in addition to follow-up surgeries.

209. On November 9, 2012 Dr. Durrani performed surgery on the Plaintiff consisting of lumbar spinal fusion from L5-S1 at Journey Lite ["the second surgery".]

210. Upon information and belief, Dr. Durrani used Infuse/BMP-2 or Puregen "off-label" in this second surgery without Plaintiff's knowledge or consent, causing harm.

211. Plaintiff continued to receive postoperative care from CAST after this second surgery.

212. Plaintiff continued to follow-up with CAST until April 2013.

213. Currently, Plaintiff is suffering from extreme difficulty in turning his head and suffers from continuous severe back pain.

214. Upon information and belief, the surgery performed by Dr. Durrani was medically unnecessary and improperly performed.

215. As a direct and proximate result of these surgeries and Dr. Durrani's negligence, the Plaintiffs have suffered harm.

216. Plaintiffs did not become aware of Dr. Durrani's use of Infuse/BMP-2 until legal counsel reviewed Plaintiffs' bills.

TAMMY JONES

217. Mrs. Jones visited Dr. Durrani at CAST and was told by Dr. Durrani during her first visit that she needed emergency surgery.

218. On or about February 22, 2013, Dr. Durrani performed a spinal fusion and implanted hardware in Mrs. Jones at Journey Lite.

219. Upon information and belief, during this surgery, Dr. Durrani used Infuse/BMP-2 and/or Puregen, without Mrs. Jone's knowledge or consent, causing Ms. Jones harm.

220. Immediately following the surgery, while still at Journey Lite, Mrs. Jones was taken from the recovery room back into surgery because of protruding hardware.

221. Upon information and belief, during this surgery, Dr. Durrani used Infuse/BMP-2 and/or Puregen, without Mrs. Jones's knowledge or consent, causing Ms. Jones harm.

222. Mrs. Jones followed up with Dr. Durrani at CAST.

223. Mrs. Jones has sought treatment from Dr. Tann Nichols with the Mayfield Clinic.

224. Mrs. Jones's pain is now worse than it was prior to surgery.

225. On or about December 11, 2013, Mrs. Jones's hardware had to be removed and replaced by Dr. Nichols.

226. Mrs. Jones now cannot sleep, cannot sit, and cannot walk or stand for long periods of times.

227. Mrs. Jones now relies on other family members to do all of the shopping, cooking, and cleaning, and is disappointed that she can no longer be independent.

228. Upon information and belief, the surgeries performed by Dr. Durrani were medically unnecessary and/or improperly performed.

229. As a direct and proximate result of Dr. Durrani's negligence and the Defendants Negligence Mrs. Jones has suffered harm

230. Mrs. Jones did not become aware of Dr. Durrani's use of Infuse/BMP-2 or PureGen until she contacted her undersigned counsel.

JEFFREY MCCLURE

231. Plaintiff sought treatment with Dr. Durrani in 2010 for pain in his lower back.

232. Dr. Durrani recommended immediate spinal fusion surgery.

233. On November 10, 2010 Dr. Durrani performed surgery on Plaintiff at West Chester Medical Center.

234. Plaintiff's pain began to increase following surgery. He continued to follow up with Dr. Durrani and complain to him about the pain. Dr. Durrani told him to give it time and let it heal.

235. Plaintiff continued to follow up because of his pain. Dr. Durrani recommended another surgery. He told him that there was a buildup of scar tissue that needed to be removed.

236. On January 25, 2013 Dr. Durrani performed an L-5 S1 hemilaminectomy surgery on Plaintiff at Journey Lite.

237. Immediately following his second surgery, Plaintiff's pain increased.

238. Upon hearing that Plaintiff was still experiencing pain and discomfort, Dr. Durrani recommended yet another surgery only a few months later.

239. On June 28, 2013 Dr. Durrani performed a transoraminal lumbar interfody fusion surgery on Plaintiff at Journey Lite.

240. Plaintiff continued to follow up and seek treatment with Dr. Durrani through August of 2013. He continued to complain of constant pain and seek help from Dr. Durrani.

241. Plaintiff now must wear a back and leg brace at all times due to pain and damage in his sciatic nerve.

242. Plaintiff lives with constant pain and discomfort as a result of his three surgeries performed by Dr. Durrani.

243. Upon information and belief, Dr. Durrani used Infuse/BMP-2 "off-label," without Plaintiff's knowledge or consent, causing Plaintiff harm.

244. Upon information and belief, the surgeries performed by Dr. Durrani were medically unnecessary and improperly performed.

245. As a direct and proximate result of these surgeries and Dr. Durrani's actions, Plaintiff has suffered harm.

246. Plaintiff did not become aware of Dr. Durrani's use of Infuse/BMP-2 in him until he contacted his undersigned counsel.

TONIA MCQUERY

247. In 2007, Tonia McQueary was referred to Dr. Durrani after she began to experience pain in her head and neck.

248. In July 2007, Dr. Durrani performed surgery on the Plaintiff consisting of a discectomy and spinal fusion from C6-C7 at Christ Hospital ["the first surgery"].

249. Upon information and belief, Dr. Durrani used BMP-2/Infuse or Puregen "off-label" in this first surgery without Plaintiff's knowledge or consent, causing harm.

250. Following the first surgery, Mrs. McQueary continued her treatment with Dr. Durrani.

251. Sometime between July 2007 and March 2009, Dr. Durrani performed surgery on the Plaintiff consisting of a T7-T10 fusion at Christ Hospital ["the second surgery"].

252. Upon information and belief, Dr. Durrani used BMP-2/Infuse or Puregen "off-label" in this second surgery without Plaintiff's knowledge or consent, causing harm.

253. Mrs. McQueary continued to treat with Dr. Durrani, and when CAST was opened in early 2009 she treated with him through his CAST offices.

254. In March 2009, Dr. Durrani performed surgery on the Plaintiff consisting of a C7-T1 fusion at West Chester Hospital ["the third surgery"].

255. Upon information and belief, Dr. Durrani used BMP-2/Infuse or Puregen "off-label" in this third surgery without Plaintiff's knowledge or consent, causing harm.

256. Following the third surgery, Mrs. McQueary continued her treatment through Dr. Durrani and CAST.

257. In July 2009, Dr. Durrani performed surgery on the Plaintiff consisting of an L5-S1 fusion at West Chester Hospital ["the fourth surgery"].

258. Upon information and belief, Dr. Durrani used BMP-2/Infuse or Puregen "off-label" in this fourth surgery without Plaintiff's knowledge or consent, causing harm.

259. During this surgery, Dr. Durrani left a drill bit inside of the Plaintiff.

260. In December 2009, an MRI performed at Christ Hospital confirmed that Dr. Durrani had left a drill bit inside of the Plaintiff. When Plaintiff asked Dr. Durrani about this mistake, he denied it.

261. Shortly thereafter, Dr. Durrani scheduled Mrs. McQueary for a hardware revision surgery, denying that the purpose was to remove the drill bit. In fact, removing the drill bit was one of Dr. Durrani's purposes.

262. In January 2010, Dr. Durrani performed a revision surgery on the Plaintiff at West Chester Hospital ["the fifth surgery"].

263. Upon information and belief, Dr. Durrani used BMP-2/Infuse or Puregen "off-label" in this fifth surgery without Plaintiff's knowledge or consent, causing harm.

264. Following the fifth surgery, Mrs. McQueary continued her treatment with Dr, Durrani and CAST and another surgery was scheduled.

265. In August 2010, Dr. Durrani performed surgery on the Plaintiff consisting of a T1-T2 fusion at West Chester Hospital ["the sixth surgery"].

266. Upon information and belief, Dr. Durrani used BMP-2/Infuse or Puregen "off-label" in this sixth surgery without Plaintiff's knowledge or consent, causing harm.

267. Following the sixth surgery, Mrs. McQueary continued her treatment with Dr. Durrani and CAST.

268. In February 2011, Dr. Durrani performed surgery on the Plaintiff consisting of a T1-T6 discectomy and fusion at West Chester Hospital ["the seventh surgery"].

269. Upon information and belief, Dr. Durrani used BMP-2/Infuse or Puregen "off-label" in this seventh surgery without Plaintiff's knowledge or consent, causing harm.

270. Following the seventh surgery, Mrs. McQueary continued her treatment with Dr. Durrani and CAST.

271. In January 2012, Dr. Durrani performed surgery on the Plaintiff consisting of a C5-C6 fusion at Journey Lite's facility in Dayton, Ohio ["the eighth surgery"].

272. Upon information and belief, Dr. Durrani used BMP-2/Infuse or Puregen "off-label" in this eighth surgery without Plaintiff's knowledge or consent, causing harm.

273. Following the eighth surgery, Mrs. McQueary continued her treatment with Dr. Durrani and CAST.

274. In August 2012, Dr. Durrani performed surgery on the Plaintiff consisting of a L5-S1 laminectomy at Journey Lite's facility in Dayton, Ohio ["the ninth surgery"].

275. Upon information and belief, Dr. Durrani used BMP-2/Infuse or Puregen "off-label" in this ninth surgery without Plaintiff's knowledge or consent, causing harm.

276. Following the ninth surgery, Mrs. McQueary continued her treatment with Dr. Durrani and CAST.

277. In March 2012, Dr. Durrani performed surgery on the Plaintiff consisting of an operation on her leg at Journey Lite's facility in Cincinnati ["the tenth surgery"].

278. Recent MRIs performed in September 2013 show that Mrs. McQueary has two new herniated discs in her T-Spine, an area that Dr. Durrani operated on extensively between 2007 and 2010.

279. Upon information and belief, the surgery performed by Dr. Durrani was medically unnecessary and improperly performed.

MARY RAVENSCRAFT

280. Around January 2013, Plaintiff visited her rheumatologist, Dr. Ford, for lower back pain.

281. Dr. Ford then referred Plaintiff to Dr. Durrani.

282. Around this same time, Plaintiff attended an initial consultation with Dr. Durrani at CAST in Blue Ash.

283. During this consultation, Dr. Durrani told Plaintiff she had a pinched nerve at L5. He further stated he would remove the disk and put 2 screws in to support the vertebrae.

284. Dr. Durrani operated on Plaintiff on February 15, 2013 at Journey Lite. Specifically Dr. Durrani operated at L5-S1, conducting a discectomy, transforaminal interbody fusion, posterior fusion, posterior spinal instrumentation, and a TLIF.

285. Dr. Durrani used Puregen in Plaintiff's surgery, without Plaintiff's knowledge or consent, causing Plaintiff harm.

286. Specifically, Plaintiff now experiences severe pain in her lower back.

287. Following the surgery, Plaintiff continued treating with Dr. Durrani at CAST and Journey Lite until June of 2013, around the time Dr. Durrani was arrested.

288. Since treating with Dr. Durrani, Plaintiff has seen Dr. Joel Sorger at Wellington Orthopedics, who stated he completely disagreed with Dr. Durrani's diagnosis of her and recommendation she undergo lumbar spine surgery.

289. Therefore, upon information and belief, the surgery performed by Dr. Durrani was medically unnecessary and/or improperly performed.

290. As a direct and proximate result of Dr. Durrani's treatment, Plaintiff has suffered harm.

DANIEL WEBBER

291. On December 2, 2010, Plaintiff's primary care physician Dr. Michael Gleske, sent Mr. Webber for an MRI of the lumbar and cervical spine.

292. On or about December 17, 2010, Mr. Webber was referred to Dr. Bradbury Skidmore, a neurosurgeon for the Mayfield Clinic in Crestview Hills, Kentucky.

293. The MRI stated "at the T12-L1 and L1-L2 levels as well as the L2-L3 levels, the intervertebral discs are normal. At the L3-L4 level, there are endplate degenerative changes. There are posterior

osteophytes and there are facet degenerative changes. There is no evidence for significant central canal or neural foraminal narrowing. At the L4-L5 level, there is only minimal right neural foraminal narrowing. At the l5-S1 level, the intervertebral disc is normal. There are mild facet degenerative changes.

294. Dr. Skidmore reviewed the MRI results and told Plaintiff surgery was not necessary.

295. On May 23, 2011, Plaintiff had an injury at work.

296. On May 23, 2011 , Plaintiff went to St. Elizabeth Medical center Emergency Department in Edgewood, Kentucky. At that time, a CT of the cervical spine without contrast, a CT of the head without contrast and an x-ray of the elbow left AP lateral and obliques were ordered.

297. The impression of the x-ray of the elbow had negative findings.

298. The impression of the CT of the head stated no acute abnormality of the brain is seen without evidence of intracranial injury.

299. The impression of the CT scan of the cervical spine (which included axial scans throughout the cervical spine) was described as "a partial fusion of the C4 and C5 vertebral bodes. There is mild/moderate disk space narrowing at C5-C6 and C6-C7. No fracture is seen. No significant prevertebral soft tissue soft tissue swelling is seen. There is anterior and posterior disc margin spurring, most prominent C5-C6 and C6-C7. There is moderate left-sided neural foraminal narrowing at C3-C4, moderate right-sided narrowing at C5-C6 and moderate bilateral neural foraminal narrowing at C6-C7.

300. The final impression for the CT scan of the cervical spine on May 23, 2011 was degenerative changes. No fracture.

301. In October of 2011, Dr. Michael Gieske ordered an MRI of the cervical spine without contrast and an MRI of the left shoulder without contrast for neck and left shoulder pain, respectively.

302. On or around October 18, 2011, Mr. Webber was seen by Dr. Durrani.

303. On October 18, 2011, Dr. Durrani dictated and electronically approved a letter to Dr. Gieske, stating Dr. Durrani's assessment of Mr. Webber included the following comments, "severe restriction of the cervical spine range of motion due to pain and that all movements of the neck were "extremely painful."

304. Dr. Durrani further stated, "the sensory examination shows clear sensory paresthesias all the way from C6 and C7 predominantly and even somewhat C8 distribution as well."

305. Dr. Durrani's statement is false and misleading since there are only seven (7) vertebrae that make up the cervical spine.

306. Dr. Durrani cites his review of the MRIs of the cervical spine as showing "a congenitally fused segment of C4-C5. There is a large disk herniation of C4-C4 and a large disk herniation of C5-C6 and C6-C7. The axial images show there is a complete foraminal stenosis at C6-C6 bilaterally, complete foraminal stenosis at C7-C7 bilaterally and on the C3-C4 it is on the left side."

307. Dr. Durrani further stated that Plaintiff had severe cervical spine stenosis C3-C4, C5-C6, C6-C6.: This statement does not reconcile with the MRI and CT results.

308. During the first office visit at CAST, Durrani told Plaintiff that "I can fix you" and recommended surgery.

309. Dr. Durrani marketed his skills and promised the surgery would be "minimally invasive."

310. Dr. Durrani and CAST scheduled the first surgery in the beginning of January 2012 and then the office called and said Plaintiff needed to pay five hundred dollars towards the procedure before it could be done.

311. Plaintiff paid the five hundred dollars – then got another call from CAST stating a change in the surgery date to the 19th of January and hospital change as well from UC Hospital to Riverview Hospital in Dayton, Ohio.

312. On January 19, 2012, Defendants performed cervical spine surgery on Plaintiff at Riverview on C6-C7 [the "first surgery"].

313. During the first surgery, Defendants experimentally used BMP-2/Infuse without Plaintiff's knowledge or consent.

314. During the first surgery, Defendants also did no use the LT-CAGE.

315. Plaintiff developed severe headaches and the physical therapist said to stop all therapy until seen again by Durrani.

316. Durrani sent Plainiff for yet another MRI. After those results came back, Durrani suggested a second surgery C-3 and C-4, "due to stress."

317. The first surgery had no effect on the Plainitff and he was still in severe pain.

318. Plaintiff's medical condition as a result of Defendants conduct was extreme and horrible, but Durrani continued to falsely document at CAST progress notes that Plaintiff was improving.

319. On May 3, 2012, Defendants performed cervical spine surgery on Plaintiff at Journey Lite on C3-C4 [the "second surgery"].

320. Journey lite didn't have a neck brace or leg/compression stockings since it was a center for weight lost treatments.

321. During the second surgery, Defendants inserted hardware into Plaintiff's cervical spine.

322. During the second surgery, Defendants experimentally used BMP-2/Infuse without Plaintiff's knowledge or consent.

323. Upon information and belief, the first and second were medically unnecessary.

324. After the second surgery, on or about May 21, 2012 Plaintiff was rushed to the Emergency Room at St. Elizabeth Hospital in Edgewood with severe leg pain and trouble walking.

325. Plaintiff's follow up with Durrani at CAST included yet another MRI.

326. Durrani stated "Can you live with the pain? If not we can do a 3rd surgery."

327. Plaintiff declined and left CAST and has not returned.

328. Plaintiff went back to his PCP and was referred for a second opinion with a Dr. Raj Kakalpudi on April 3, 2013 at Commonwealth Orthopedic.

329. Upon information and belief, the surgeries were unnecessary and further medical treatment and pain management will be required.

330. But for Defendants conduct and negligence regarding the surgeries, the Plaintiff's ongoing and future pain management.

331. Plaintiff is now permanently disabled, disfigured, harmed, immobile and in constant pain.

332. Plaintiff continues suffering to this day from severe neck pain, back pain, radiating arm pain and headaches.

333. Plaintiff has pain that won't go away and continues to increase over time.

334. Plaintiff doesn't sleep and at times, becomes severely depressed. He does not function nin the way he once did before surgery with Defendants.

335. Plaintiff can no longer work and can no longer do plumbing, which was his occupation for 31 years, causing a financial hardship on his wife and Plaintiff.

336. Plaintiff's cannot pay their bills and this is affecting his credit.

REGINA WESLEY

337. In early 2012, Plaintiff's primary care physician referred her to Dr. Durrani at his CAST offices.

338. At the time, Plaintiff had been experiencing pain in her back for several months.

339. During her first consultation with Dr. Durrani, x-rays were taken at the CAST office.

340. Dr. Durrani reviewed the x-rays, telling the Plaintiff that they were "very bad," and that "there [was] nothing good about this." He explained to the Plaintiff that one of her previously implanted Harrington rods had broken and migrated into her shoulder, and that her previous spinal fusion had not "taken."

341. Dr. Durrani scheduled Plaintiff for several pre- and postoperative appointments and surgeries, telling her that she would be "good as new".

342. On July 6, 2012 Dr. Durrani performed surgery on the Plaintiff that was scheduled to be a fusion of the lumbar spine with tailbone reconstruction at West Chester Hospital ["the first surgery"].

343. Upon information and belief, Dr. Durrani used Infuse/BMP-2 or Puregen "off-label" in this surgery without Plaintiff's knowledge or consent, causing harm.

344. Upon information and belief, the actual surgery performed by Dr. Durrani was not the lumbar fusion with tailbone construction, and was in fact something altogether different.

345. Immediately after the surgery, Dr. Durrani informed Plaintiff's husband that everything went well and that Plaintiff was in recovery.

346. However, Plaintiff's husband was later informed that Plaintiff was in fact admitted to the ICU as the result of several premature ventricular contractions that occurred during surgery.

347. After plaintiff was released, and prior to her second surgery, Plaintiff learned that she had contracted a MRSA infection that needed to be treated prior to the second surgery.

348. On September 5, 2012, Dr. Durrani performed surgery on the Plaintiff that was supposed to consist of the removal of the broken Harrington rod at West Chester Hospital.

349. However, immediately prior to the surgery Dr. Durrani elected to instead perform a cervical fusion and disc replacement ["the second surgery"].

350. Upon information and belief, Dr. Durrani used Infuse/BMP-2 or Puregen "off-label" in this second surgery without Plaintiff's knowledge or consent, causing harm.

351. During her postoperative meeting with Dr. Durrani, he informed the Plaintiff that her neck was "not that bad" after all, and that he had only replaced one disc.

352. Plaintiff began to suffer from pains in her neck, and continued to suffer from pains in her tailbone, following this surgery. Dr. Durrani informed the Plaintiff that this was "all part of the healing process".

353. On April 24, 2013, Dr. Durrani performed surgery on the Plaintiff consisting of further cervical fusions with disc replacement at Journey Lite Hospital ["the third surgery"].

354. Upon information and belief, Dr. Durrani used Infuse/BMP-2 or Puregen "off-label" in this third surgery without Plaintiff's knowledge or consent, causing harm.

355. When Plaintiff questioned Dr. Durrani as to why this surgery was necessary given his previous assessment that her cervical spine was "not that bad", he told the Plaintiff that he had been unable to reach the rest of her neck from the location of the second surgery's incision due to excessive damage.

356. However, Plaintiff's incision from the third surgery is only an inch away from the incision from the second surgery.

357. During Plaintiff's recovery from this third surgery, Plaintiff received a billing notice showing that she owed $1200 to Journey Lite. When she called them to ask about the bill, Journey Lite informed

Plaintiff that she would not owe that money because she "was not informed of the additional metal" that Dr. Durrani had placed in her neck.

358. On July 23, 2013, Dr. Durrani performed surgery on the Plaintiff to address the broken Harrington rod at Journey Lite Hospital ["the fourth surgery"].

359. Upon information and belief, Dr. Durrani used Infuse/BMP-2 or Puregen "off-label" in this fourth surgery without Plaintiff's knowledge or consent, causing harm.

360. Since these surgeries, Plaintiff has suffered and continues to suffer from severe pain in her hands, legs, back, neck, shoulders, and feet. She continues to have regular muscle spasms that are often accompanied by numbness.

361. Plaintiff continues to participate in a pain management regimen that has her taking up to 15 painkillers a day; this regimen has only served to partially defray Plaintiff's pain.

362. Finally, Plaintiff is extremely limited in her mobility and must resort to relying on a walker or cane for short-term mobility. For anything more substantial, Plaintiff is often confined to a wheelchair.

363. Subsequent treating physicians have informed Plaintiff that she "will be in pain for the rest of [her] life."

364. Upon information and belief, the surgery performed by Dr. Durrani was medically unnecessary and improperly performed.

365. As a direct and proximate result of these surgeries and Dr. Durrani's negligence, the Plaintiffs have suffered harm.

366. Plaintiffs did not become aware of Dr. Durrani's use of Infuse/BMP-2 until legal counsel reviewed Plaintiffs' bills.

HOLLY REIFENBERGER

367. Ms. Reifenberger was suffering with severe neuropathy in her left leg, lower back pain, and stiff neck pain.

368. Ms. Reifenberger saw a T.V. commercial for Dr. Durrani and made an appointment to

visit him.

369. Ms. Reifenberger first visited with Dr. Durrani at CAST.

370. During her first appointment with Dr. Durrani, Dr. Durrani examined an MRI Ms. Reifenberger had taken at Bethesda North.

371. Dr. Durrani told Ms. Reifenberger that she would need surgery right away, and would eventually need a second surgery.

372. In or around May 2012, Dr. Durrani performed a C5-C6 cervical fusion on Ms. Reifenberger at West Chester Hospital.

373. Upon information and belief, during this surgery, Dr. Durrani used Infuse/BMP-2 and/or Puregen, without Ms. Reifenberger's knowledge or consent, causing Ms. Reifenberger harm.

374. Following the surgery, Ms. Reifenberger still experienced neck pain, was not able to turn her neck all of the way, had difficulty swallowing, had a constant cough and had to clear her throat, experienced back pain, and experienced a loss of flexibility.

375. Further following the surgery, Ms. Reifenberger followed up with Dr. Durrani at CAST.

376. Dr. Durrani told Ms. Reifenberger she needed to undergo back surgery.

377. Dr. Durrani further told Ms. Reifenberger that her heck pain should be resolved.

378. Ms. Reifenberger experienced an infection in the scar on her neck.

379. Dr. Durrani treated the infection in the scar by draining it two to three times.

380. Dr. Durrani performed an L4-5 Fusion and Laminectomy on Ms. Reifenberger at Journey Lite.

381. Upon information and belief, during this surgery, Dr. Durrani used Infuse/BMP-2 and/or Puregen, without Ms. Reifenberger's knowledge or consent, causing Ms. Reifenberger harm.

382. Following this surgery, Ms. Reifenberger followed up with Dr. Durrani at CAST until the

day of Dr. Durrani's arrest.

383. Ms. Reifenberger now experiences constant pain.

384. Ms. Reifenberger experiences pain when she looks side to side.

385. Ms. Reifenberger is unable to sit for long periods of time and has difficult bending.

386. Ms. Reifenberger further has difficulty performing daily household chores.

387. Ms. Reifenberger now treats with Dr. Michael Danko at Advanced Spine for pain management, and her primary care physician, Dr. Michael Trombly.

388. Upon information and belief, the surgeries performed by Dr. Durrani were medically unnecessary and/or improperly performed.

389. As a direct and proximate result of Dr. Durrani's negligence and the Defendants Negligence Ms. Reifenberger has suffered harm

390. Ms. Reifenberger did not become aware of Dr. Durrani's use of Infuse/BMP-2 or PureGen until she contacted her undersigned counsel.

CLASS ALLEGATIONS

391. Mary Ravenscraft maintains this action on behalf of herself and all patients who, as of the filing of this complaint, had PureGen placed in them by Dr. Durrani at Journey Lite.

392. The members of this putative class are so numerous that joinder of individual claims is impracticable. Moreover, there are significant questions of fact and law common to the members of the putative class, such as the withholding of itemized billing.

393. Mary Ravenscraft's claims are typical of the claims of the putative class.

394. Mary Ravenscraft will fairly and adequately represent the putative class because she has the class members' interest in mind, her claim is co-extensive with and identical to those of the class, and because they are represented by qualified counsel.

395. A class action is superior to other available methods for fair and efficient adjudication of these claims since individual joinder of all members of the putative class is impracticable and most members of the class are without the financial resources necessary to pursue this matter. Even if some members of the class could afford to litigate their claims separately, such a result would be unduly burdensome to the courts in which the individual cases would proceed. Individual litigation increases the time and expense of resolving a common dispute concerning Journey Lite's actions towards a class of patients.

396. The putative class may be certified pursuant to Rule 23(a) of the Ohio Rules of Civil Procedure because Defendants have acted on grounds generally applicable to the putative class thereby making final injunctive relief and corresponding declaratory relief appropriate with respect to the claims raised by the class.

397. Plaintiffs would like a short period of initial discovery on the issue of the class certification.

CLASS MEMBERS

398. Plaintiff sues on her own behalf and on behalf of all persons under Civil Rule 23 of the Ohio Rules of Civil Procedure.

399. The members of the Class are every person who underwent surgery by Dr. Durrani at Journey Lite in which he used PureGen, during the Class Period, in which Journey Lite was the surgical or medical facility for a patient from 2011 through the present.

400. The Class as defined above is identifiable, unambiguous, and based on objective information and criteria. The following persons shall be excluded from the Class: (a) Defendants, and its owners, subsidiaries and affiliates; (b) all persons who make a timely election to be excluded from the proposed Class; (c) governmental entities; and (d) the judge(s) to whom this case is assigned and any immediate family members thereof.

CLASS PERIOD

401. The Class period is from approximately 2011 up to and including the date of filing.

COUNT I - FRAUD

402. Ohio Administrative Code 3701-83-07(A)(5) states, "Each patient shall receive, if requested, a detailed explanation of facility charges including an itemized bill for services rendered.

403. The bills sent to Plaintiff, after multiple requests, were in violation Ohio Administrative Code 3701-83-07(A)(5).

404. Upon information and belief, Plaintiff believes that Dr. Durrani implanted Puregen into Plaintiff.

405. Even after Plaintiff's Counsel and the Ohio Attorney General requested itemized billing, Journey Lite still did not provide an itemized breakdown of the charges; instead Journey Lite continued to provide "Account Ledgers," which contained barebones "Insurance Billing" and "Insurance Payments."

406. Due to Journey Lite's downright refusal to comply with Plaintiff's request for itemized billing, Plaintiff has been forced to file a class action suit against Journey Lite's for their egregious billing practices.

407. The bills sent by Journey Lite to Plaintiff falsely represented that Plaintiff's surgeries were appropriately indicated, performed, and medically necessary in contra-indication of the standard of care.

408. Upon information and belief, Plaintiff believes the bills requested by Plaintiff will indicate that Journey Lite Hospital falsely represented that Plaintiff's surgery was appropriately indicated, performed, and medically necessary in contra-indication of the standard of care.

409. The bills were sent to Plaintiff's insurance company with the knowledge of Journey Lite that in fact Plaintiff's surgeries were not appropriately billed and documented and that the services rendered at Journey Lite associated with Dr. Durrani were not appropriate.

410. Plaintiffs relied on the facility holding Dr. Durrani out as a surgeon and allowing him to perform surgeries at its health care facility as assurance the facility was overseeing Dr. Durrani, vouching for his surgical abilities, and further was appropriately billing Plaintiffs for Journey Lite's services in association with Dr. Durrani's surgeries.

411. As a direct and proximate result of this reliance on the billing of Journey Lite, Plaintiff incurred medical bills that she otherwise would not have incurred.

412. Journey Lite also either concealed from Plaintiff that they knew about Dr. Durrani, including that Infuse/BMP-2 and/or Puregen would be used in Plaintiff's surgeries, or misrepresented to Plaintiff the nature of the surgeries and the particular risks that were involved therein.

413. Journey Lite's concealments and misrepresentations regarding Puregen and the nature and risks of Plaintiff's surgeries were material facts.

414. Because of its superior position and professional role as a medical service provider, Journey Lite had a duty to disclose these material facts to Plaintiffs and a duty to refrain from misrepresenting such material facts to Plaintiffs.

415. Journey Lite intentionally concealed and/or misrepresented said material facts with the intent to defraud Plaintiff in order to induce Plaintiff to undergo the surgeries, and thereby profited from the surgeries and procedures Dr. Durrani performed on Plaintiff at Journey Lite.

416. Plaintiff was unaware that Puregen would be used in Plaintiff's surgeries and therefore, was unaware of the health risks of Puregen's use in Plaintiff's spine.

417. Had Plaintiff known before Plaintiff's surgery that Puregen would be used in Plaintiff's spine and informed of the specific, harmful risks flowing there from, Plaintiff would not have undergone the surgeries with Dr. Durrani at Journey Lite.

418. Plaintiff is still awaiting itemized billing from Journey Lite Hospital reflecting the exact totals charged for the use of Puregen on Plaintiff.

419. As a direct and proximate result of the fraud upon Plaintiffs by Journey Lite, Plaintiff sustained all damages requested in the prayer for relief.

420. The bills were sent to Plaintiff's insurance company with the knowledge of Journey Lite that in fact Plaintiff's surgeries were not appropriately billed and documented and that the services rendered at Journey Lite associated with Dr. Durrani were not appropriate.

421. The bills sent by Journey Lite to Plaintiff falsely represented that Plaintiff's surgeries were appropriately indicated, performed and medically necessary in contra-indication of the standard of care.

422. Plaintiff relied on the facility holding Dr. Durrani out as a surgeon and allowing him to perform surgeries at its health care facility as assurance the facility was overseeing Dr. Durrani, vouching for his surgical abilities, and further was appropriately billing Plaintiff for Journey Lite's services in association with Dr. Durrani's surgeries.

423. As a direct and proximate result of this reliance on the billing of Journey Lite, Plaintiff incurred medical bills that she otherwise would not have incurred.

424. Journey Lite also either concealed from Plaintiff that Puregen would be used in Plaintiff's surgeries, or misrepresented to Plaintiff the nature of the surgeries and the particular risks that were involved therein.

425. Journey Lite's concealments and misrepresentations regarding Puregen and the nature and risks of Plaintiff's surgeries were material facts.

426. Because of its superior position and professional role as a medical service provider, Journey Lite had a duty to disclose these material facts to Plaintiff and a duty to refrain from misrepresenting such material facts to Plaintiff.

427. Journey Lite intentionally concealed and/or misrepresented said material facts with the intent to defraud Plaintiff in order to induce Plaintiff to undergo the surgery, and thereby profited from the surgery and procedure Dr. Durrani performed on Plaintiff at Journey Lite.

428. Plaintiff was unaware that Puregen would be used in Plaintiff's surgery and therefore, was unaware of the health risks of Puregen's use in Plaintiff's spine.

429. Had Plaintiff known before Plaintiff's surgery that Puregen would be used in Plaintiff's spine and informed of the specific, harmful risks flowing therefrom, Plaintiff would not have undergone the surgery with Dr. Durrani at Journey Lite.

430. As a direct and proximate result of the fraud upon Plaintiff by Journey Lite, Plaintiff sustained all damages requested in the prayer for relief.

431. Journey Lite did not disclose to Plaintiff their intent to use Puregen, and further, did not disclose their intent to use PureGen in a way not approved by the FDA. **PUREGEN WAS NEVER APPROVED BY THE FDA FOR USE IN HUMANS.**

432. Journey Lite used Puregen in Plaintiff in manners not approved by Alphatec or the FDA.

433. Plaintiffs were not informed by Journey Lite that Puregen was used in surgery.

434. Plaintiffs would not have allowed Puregen to be used by in their surgeries in a manner that was not approved by the FDA or Alphatec, PureGen's manufacturer.

435. Plaintiffs would not have consented to the use of Puregen in their body if informed of the risks by any Jounrey Lite personnel.

436. The written informed consent of Journey Lite signed by Plaintiffs lacked the disclosure of PureGen use in their procedure.

437. Plaintiffs never received a verbal disclosure of Puregen from any Journey Lite personnel.

438. Journey Lite also either concealed from Plaintiffs that Puregen would be used in Plaintiffs' surgeries, or misrepresented to Plaintiffs the nature and necessity of the surgeries and the particular risks involved therein.

439. Journey Lite concealments and misrepresentations, through their employees, regarding Puregen and the nature, necessity, and risks of Plaintiff's surgery were material facts.

440. Because of its superior position and professional role as a medical service provider, Journey Lite had a duty to disclose these material facts to Plaintiff and a duty to refrain from misrepresenting such material facts to Plaintiff.

441. Journey Lite intentionally concealed and/or misrepresented said material facts with the intent to defraud Plaintiff in order to induce Plaintiff to undergo the surgery, and thereby profited from the surgeries and procedures Dr. Durrani performed on Plaintiff at Journey Lite

442. Plaintiffs were unaware that Puregen would be used in Plaintiffs' surgery and therefore, were unaware of the health risks of Puregen use in Plaintiffs' spine.

443. Journey Lite consent forms contain no mention of Puregen.

444. Had Plaintiffs known before Plaintiffs' surgeries that Puregen would be used in Plaintiffs' spine and informed of the specific, harmful risks flowing therefrom, Plaintiffs would not have undergone the surgery at Journey Lite.

445. As a direct and proximate result of Journey Lite concealments and/or misrepresentations regarding Puregen, and the nature and necessity of the surgeries at Journey Lite, Plaintiffs sustained, inter alia, economic, and non-economic (including physical, emotional) damages.

COUNT II: NEGLIGENCE

446. Journey Lite owed their patient, Plaintiff, the duty to exercise the degree of skill, care, and diligence an ordinarily prudent health care provider would have exercised under like or similar circumstances.

447. Journey Lite breached their duty by failing to exercise the requisite degree of skill, care and diligence that an ordinarily prudent health care provider would have exercised under same or similar circumstances through, among other things, negligent diagnosis, medical mismanagement and mistreatment of Plaintiff, including but not limited to improper selection for surgery, improper performance of the surgery, and improper follow-up care addressing a patient's concerns.

448. As a direct and proximate result of the aforementioned negligence and deviation from the standard of care on the part of the Defendant Journey Lite, Plaintiff sustained severe and grievous injuries, prolonged pain and suffering, emotional distress, humiliation, discomfort, loss of enjoyment of life, and loss of ability to perform usual and customary activities and incurred substantial medical expenses and treatment.

COUNT III: OHIO CONSUMER SALES PROTECTION ACT

449. Although the Ohio Consumer Sales Protection statutes O.R.C 1345.01 et seq. exempts

physicians, a transaction between a hospital and a patient/consumer is not clearly exempted.

450. Journey Lite services rendered to Plaintiffs constitute a "consumer transaction" as defined in ORC Section 1345.01(A).

451. Journey Lite omitted suppressed and concealed from Plaintiffs facts with the intent that Plaintiffs rely on these omissions, suppressions and concealments as set forth herein.

452. Journey Lite Health misrepresentations, and its omissions, suppressions and concealments of fact, as described above, constituted unfair, deceptive and unconscionable acts and practices in violation of O.R.C 1345.02 and 1345.03 and to Substantive Rules and case law.

453. Journey Lite was fully aware of its actions.

454. Journey Lite Health was fully aware that Plaintiffs were induced by and relied upon Journey Lite's representations at the time Journey Lite was engaged by Plaintiffs.

455. Had Plaintiffs been aware that Journey Lite's representations as set forth above were untrue, Plaintiffs would not have used the services of Defendants.

456. Journey Lite's actions were not the result of any bona fide errors.

457. As a result of Journey Lite's unfair, deceptive and unconscionable acts and practices, Plaintiffs have suffered and continues to suffer damages, which include, but are not limited to the following:

a. Loss of money paid

b. Severe aggravation and inconveniences

c. Under O.R.C. 1345.01 Plaintiff is entitled to:

    i. An order requiring Journey Lite restore to Plaintiffs all money received from Plaintiffs plus three times actual damages and/or actual/statutory damages for each violation;

ii. All incidental and consequential damages incurred by Plaintiffs;

iii. All reasonable attorneys' fees, witness fees, court costs and other fees incurred;

iv. Such other and further relief that this Court deems just and appropriate.

COUNT IV: NEGLIGENT CREDENTIALING, SUPERVISION, AND RETENTION

458. By R.C. 2305.251(B) regarding the negligent credentialing of physicians. Therein, it is provided:

a. (1) A Hospital shall be presumed to not be negligent in the credentialing of an individual who has, or has applied for, staff membership or professional privileges at the hospital pursuant to section 3701.351 of the revised code… if the hospital… proves by a preponderance of the evidence that, at the time of the alleged negligent credentialing of the individual, the hospital… was accredited by one of the following:

(a) The joint commission accreditation of healthcare organization;

(b) The American Osteopathic association;

(c) The national committee for quality assurance;

(d) The utilization review accreditation commission.

b. R.C. 2305.251(B)(1)

However, pursuant to R.C. 2305.251, Plaintiff may rebut this presumption against negligence by showing, by a preponderance of the evidence, any of the following:

(a) The credentialing and review requirements of the accrediting organization did not apply to the hospital….the individual, or the type of professional care that is the basis of the claim against the hospital…..

(b) The hospital failed to comply with all material credentialing and review

requirements of the accrediting organization that applied to the individual.

(c) The hospital through its medical staff executive committee or its governing body and sufficiently in advance to take appropriate action, knew that a **previously competent individual had developed a pattern incompetence or otherwise inappropriate behavior,** either of which indicated that the individual's staff membership, professional privileges, or participation as a provider should have been limited or terminated prior to the individual's provision of professional care to the Plaintiff.

(d) The hospital through its medical staff executive committee or its governing body and sufficiently in advance to take appropriate action, knew that a previously competent individual would provide **fraudulent medical treatment** but failed to limit or terminate the individual's staff membership, professional privileges, or participation as a provider prior to the individual's provision of professional care to the plaintiff.

459. Journey Lite Hospital negligently credentialed, supervised, and retained Dr. Durrani as a credentialed physician, violating their bylaws and JCAHO rules as fully set forth in this Complaint.

460. The Safe Medical Device Act required entities such as Journey Lite Hospital to report serious injuries, serious illnesses, and deaths related to failed medical devices to the FDA and the manufacturer; this was never done.

461. As a direct and proximate result of the negligent credentialing, supervision, and retention of Dr. Durrani, Plaintiff sustained all damages requested in the prayer for relief.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request and seek justice in the form and procedure of a jury, verdict and judgment against Defendants on all claims for the following damages:

1. All damages permitted under O.R.C. 1345.01 and all other applicable law;
2. All incidental costs and expenses incurred as a result of the injuries;
3. The damages to their credit as a result of their injuries;
4. Punitive damages;
5. Costs;
6. Attorneys' fees;
7. Interest;
8. All other relief to which Plaintiffs are entitled and based upon the damages sought they exceed the minimum jurisdictional amount of this Court and Plaintiffs seek in excess of $25,000.

Respectfully Submitted,

Matthew J. Hammer (#0092483)
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mhammer@ericdeters.com
Counsel for Plaintiffs

JURY DEMAND

Plaintiff makes a demand for a jury under all claims.

Matthew Hammer

COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO

REQUEST AND INSTRUCTIONS FOR ORDINARY MAIL SERVICE

Mary Ravenscraft
Plaintiff

-vs-

Journey Lite of Cincinnati, LLC
Defendant

INSTRUCTIONS TO THE CLERK

CASE NUMBER: A 1602066

IF SERVICE OF PROCESS BY CERTIFIED MAIL IS RETURNED BY THE POSTAL AUTHORITIES WITH AN ENDORSEMENT OF "REFUSED" OR "UNCLAIMED" AND IF THE CERTIFICATE OF MAILING CAN BE DEEMED COMPLETE NOT LESS THAN FIVE (5) DAYS BEFORE ANY SCHEDULED HEARING, THE UNDERSIGNED WAIVES NOTICE OF THE FAILURE OF SERVICE BY THE CLERK AND REQUESTS ORDINARY MAIL SERVICE IN ACCORDANCE WITH CIVIL RULE 4.6 (C) OR (D) AND CIVIL RULE 4.6 (E).

Matthew J. Hammer
ATTORNEY OF RECORD **(TYPE OR PRINT)**

\s\Matthew J. Hammer
ATTORNEY'S SIGNATURE

DATE

FILED
AUG 08 P 2:03
TRACY WINKLER
CLERK OF COURTS
HAMILTON COUNTY, OH

COMMON PLEAS COURT
HAMILTON COUNTY, OHIO

Mary Ravenscraft

A 1602066

CASE NO.

VS

Journey Lite of Cincinnati, LLC

WRITTEN REQUEST FOR SERVICE
TYPE OF PAPERS TO BE SERVED ARE

Complaint (Class Action)

( ) PLEASE CHECK IF THIS IS A DOMESTIC CASE

PLAINTIFF/DEFENDANT REQUESTS:

CERTIFIED MAIL SERVICE X

PERSONAL SERVICE

PROCESS SERVICE

EXPRESS MAIL SERVICE

REGULAR MAIL SERVICE

RESIDENCE SERVICE

FOREIGN SHERIFF

ON Journey Lite of Cincinnati, LLC; Serve: CT Corporation System

1300 East Ninth Street,Cleveland, OH 44114

FILED
2016 APR -8 P 2:03
COURTS
CLERK OF COURTS
HAMILTON COUNTY, OH

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